(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 821 976 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
04.02.1998 Bulletin 1998/06

(51) Int. Cl.[6]: **A61M 16/00**

(21) Application number: **97109023.8**

(22) Date of filing: **04.06.1997**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **02.08.1996 SE 9602913**

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(54) Ventilator system and method of operating a ventilator system

(57) A ventilator system and a method of operating the ventilator system is disclosed. The ventilator system comprises a ventilator (2) and a connection system (14, 16) for connecting the ventilator system to a patient (4). Parameters for a respiration gas pattern are set on the ventilator (2). Due to the influence of the connection system (14, 16) on the respiration gas pattern, the generation of the respiration gas pattern needs to be calibrated in order to ensure that the set respiratory gas pattern is delivered to the patient (4). In order to obtain calibration factors a test gas pulse is generated by an inspiration system (8) before connecting the patient (4). Measurements of the test gas pulse are made with parameter meters (28, 30, 32) at different locations in the connection system (14, 16). The parameters for the test gas pulse, as well as the measured parameters are stored in different data sets. By synchronising and subtracting measured parameter data sets from the set parameter data set, calibration factors are obtained.

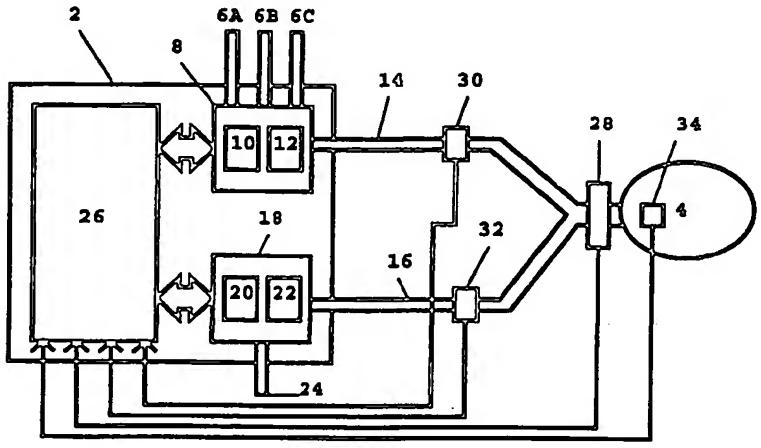

FIG. 1

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Description

The present invention relates to a method of operating a ventilator system, comprising a ventilator and a connection system for, when connected to a patient, conveying gas to and from the patient.

The present invention also relates to a ventilator system comprising an inspiration section for generating an inspirational respiratory gas pattern, a connection system for, when connected to a patient, conveying gas to and from the patient, an expiration section for generating an expirational respiratory gas pattern, a measurement system for measuring respiratory gas pattern parameters at different sites in the ventilator system and a control unit for controlling the operation of the ventilator system based on set operational parameters and measured parameters.

In the past 50 years, the development of ventilator systems (which in this application includes all respirator/ventilator systems as well as anaesthetic systems) has made rapid progress. From initially using simple mechanical piston systems to impose breathing gas on the patient at every piston stroke, todays ventilator systems can be controlled to supply a breathing gas to a patient according to a plurality of different operating modes, a physician then being able to select the operating mode deemed most suitable for the patient.

A ventilator system can be described as a ventilator with a connection system for connecting the ventilator to the patient. One known ventilator is the Servo Ventilator 300, Siemens-Elema AB, Solna, Sweden. This ventilator is equipped with a very fast and accurate gas regulation system. In practice, this means that a gas flow can be generated with an optional respiratory gas pattern. In the present application, respiratory gas pattern refers to pressure and flow characteristics over time. So pressure and flow in any given respiratory gas pattern can display predefined variations over time.

But even if the regulatory system is capable of generating a gas flow which corresponds almost exactly to the target respiratory gas pattern, it is not certain that the gas flow received by the patient has the target respiratory gas pattern. This because of the interjacent connection system, which influences the respiratory gas pattern.

The connection system can i.a. comprise tubes, humidifiers, dehumidifiers and bacterial filters. Flow resistance in gas lines and other components in the connection system influences the respiratory gas pattern in one way. The total volume taken up by the connection system influences the respiratory gas pattern in another way. This because gases are highly compressible. The influence to which the respiratory gas pattern is subjected by the connection system changes the pattern of gas flow in respect to delay and morphology (morphology here referring to variations in pressure and flow over time).

Attempts have previously been made to compensate, at least to some extent, for the influence exerted by the connection system. For example, the operational manual for the aforementioned Servo Ventilator 300, AG 0593 3.5, Siemens-Elema AB, 1993, pp. 94-98, describes compensation for the connection systems compressible volume. Compensation in this case means that the physician must set a larger minute volume for the breathing gas to be supplied to the patient in order to ensure the delivery to the patient of the target minute volume. Here, the physician is forced to make the calculations required to achieve the necessary compensation. The calculation example on page 98 in the operational manual, meant for an adult patient, shows that minute volume has to be increased by 2.5 l/m when the target minute volume was 7.5 l/m. Compensation naturally varies from case to case. The need for compensation depends in particular on the configuration of the connection system. However, the calculation example does provide an indication of the compensation needed for minute volume.

There are also other known ventilator systems offering compensation, either by a physician or by a programmed automatic function. The compensation mainly entails a determination of the connection systems compressible volume, for instance the Puritan Bennet, 7200 Series Microprocessor Ventilator, option 30/40, part number 20522A, March 1986.

However, determination of compressible volume does not really indicate how a respiratory gas pattern is actually influenced and altered by the connection system. As noted above, respiratory gas pattern refers to pressure and flow variations over time. If the flowing gas is viewed as a gas pillar passing through the connection system, it will be realized that even simple compression of the gas pillar changes the flanks of the pillar and, in particular, the pressure and flow variations over time. So, compressible volume does not indicate anything about, for instance, the way in which a target pressure increase flank for the gas pillar is influenced on its way to the patient's respiratory system. Determining compensation for the connection systems compressible volume does not therefore supply sufficient information for the use in calculating compensation of the respiratory gas pattern. As already noted, the flow of gas is also delayed in the connection system. It may even be so, that different parts of the connection system imposes different delays on the respiratory gas pattern.

In conjunction with both the diagnoses and treatment of disorders in the respiratory system (primarily the lungs) of a patient, determination of the lung's various mechanical parameters is desirable. Determination of resistance and compliance is especially important. Roughly speaking, compliance can be determined in ways similar to determinations of compressible volume in the connection system of the known ventilator systems. However, one problem is that the connection systems influence on gas flow is not fully known for the known ventilator systems, so determination of the lungs

mechanical parameters is even more uncertain. Moreover, the properties of these mechanical parameters can also influence the respiratory gas pattern.

In conjunction with the development of increasingly more accurate and exact gas generating systems in the ventilator art, the ability to determine and take into account factors for which compensation previously could not be made is also more desirable.

By using complex mathematical methods, models for the influation of each present component in the connection system can be assumed and a model for the entire connection system can be calculated mathematically and used as an overall compensating model for the connection system. However, such models require that the transfer function for each component is verified not only for the component itself but also when interacting with other components in the connection system. Since components are manufactured by several manufacturers, each component from each manufacturer must be tested and verified for a mathematical model. In practice, a physician must then program the ventilator system for each new configuration of the connection system.

Another possibility is to regard the entire connection system as an unknown transfer system, having an unknown transfer function. In an earlier Swedish patent application, SE 9500275-4, such a system is described. A test gas pulse is generated by the ventilator and the resulting gas pulse responses are measured at different sites in the ventilator system. By using the resulting gas pulse response and the test gas pulse in mathematical methods of calculation, for instance Box Jenkins model structures or similar, a transfer function can be calculated for the entire connection system. This requires the presence of fairly strong computor calculation possibilities.

An object of the invention is to set forth a method for obtaining information relating to static and dynamic influence from connection system in a relatively easy manner without exercising unnecessary calculations.

Another object of the invention is to set forth a method for obtaining more relevant information regarding the properties of a respiratory system, when connected to the ventilator system.

Yet another object of the invention is to set forth a ventilator system which in an easy manner can produce information relevant for the influence of the connection system.

The first object is achieved in accordance with the invention in that the method comprises the steps of setting a number of operational parameters for a test gas pulse, storing the set operational parameters as a first data set, delivering the test gas pulse, measuring parameters of a resulting gas pulse response, storing the measured parameters as at least one second data set and forming at least one third data set based on the first data set and the second data set, the third data set comprising information relating to the static and dynamic influence and/or properties of at least one flow path within the ventilator system.

In a straight-forward embodiment, the measured parameters are measured at one specific site in the connection system and the two data sets represent the time dependent variation of pressure flow etc at two different sites in the ventilator system (one being the target pattern and the other the resulting pattern). The third data set is formed based on the first and second data set and comprises the necessary information for determining how the connection system or at least a part of the connection system (when the measurement site cannot measure the influence of the entire connection system) has influenced the generated test gas pulse. This information may be used to calibrate the generation of respiratory gas patterns, but may also be used for determining the resistance and compressible volume in the connection system (or the specific part of the connection system).

In a more complex embodiment, the measured parameters are measured at several sites. Both partial and total influences can then be determined in the same simplistic manner. The measured parameters can be stored in several data sub-sets to the second data set or directly as several data sets.

Improvements and embodiments of the method are disclosed in the dependent claims to claim 1. In particular it is an improvement of the method to synchronise the data stored in the first and second data sets before forming the third data set. The synchronisation can be performed by including a change in the composition of the gas in the test gas pulse, such as changing the concentration of CO_2 or O_2 or any other component gas. The change in composition can also be realised as a complete change of singular gases, for instance changing from N_2O to pure O_2 or similar. The gas selected for the change depends on a number of factors, such as if the system is a straight-forward ventilator system for providing air and oxygen, or a complex anaesthetic system.

Another important improvement of the method is that the procedure is repeated after connection of a patient to the ventilator system. Hereby a fourth data set is obtained, which comprises information of the patient's influence on the complete connection system. The patient related parameters can then be determined and the generation of respiratory gas patterns can be compensated by the influence of the patient on the connection system, as well.

The other object of the invention is achieved in that the control unit of the ventilator system controls the inspiration section to generate a test gas pulse based on set operational parameters for the test gas pulse, the control unit comprising a data storage and calculation system for storing the set operational parameters as a first data set and for storing parameters measured by the measurement system as a second data set and the data storage and calculation system forming a third data

set based on the first data set and the second data set.

Improvements of the ventilator system in accordance with the invention are disclosed in the dependent claims to claim 9.

In the following an embodiment of the invention will be described in further detail referring to the figures, whereby

Fig. 1 shows a ventilator system according to the invention connected to a patient,

Fig. 2 shows a test gas pulse delivered by the ventilator system, a resulting gas pulse response and a correction diagram, and

Fig. 3 shows a control unit of the ventilator system.

Figure 1 shows a ventilator system according to the invention. The ventilator system comprises a ventilator 2 connected to a patient 4 for supplying respiratory gas to and conveying respiratory gas from the patient 4. The ventilator 2 can be connected to external gas sources via a first gas connection 6A, a second gas connection 6B and a third gas connection 6C. Via the gas connections 6A-6C different gases can be supplied to the ventilator 2. Air, oxygen, laughing gas and other gases can be supplied, depending on the purpose for supplying respiratory gas to the patient 4. The gases supplied to the ventilator 2 are led to an inspiration section 8 which comprises control elements such as valves and a mixing chamber for controlling flow, pressure and composition (over time) of a respiratory gas. The control elements and their operation, are well known. For instance the Servo Ventilator 300, described above, comprises such control elements. The inspiration section 8 further comprises a first flow meter 10 for measuring the flow generated by the inspiration section 8 and a first pressure gauge 12 for measuring the pressure generated by the inspiration section 8. The first flow meter 10 can comprise one flow sensor for the total flow or several flow sensors, one for each gas supplied. In the latter case the sum of the flow sensors represent the total flow measured by the first flow meter 10.

During normal operation, respiratory gas is conducted via an inspiration line 14 to the patient 4 for providing controlled or supported inspiration phases.

During expiration, respiratory gas is conveyed from the patient 4 via an expiration line 16 to an expiration section 18 in the ventilator 2. The expiration section 18 comprises a valve (not shown) for controlling the expiration flow and also for controlling the pressure in the expiration line 16.

The expiration section 18 also comprises a second flow meter 20 and a second pressure gauge 22 for measuring the flow and the pressure at the end of the expiration line 16.

After passing the expiration section 18, the expired gas is conducted via an expiration outlet 24 either to ambient atmosphere or to an evacuation system (not shown).

The operation of the ventilator 2 is controlled by a control unit 26 which can comprise analogue control systems or one or several microprocessors for controlling the inspiration section 8 and the expiration section 18.

Pressure, flow and/or composition of the respiratory gas can also be measured in a first patient parameter meter 28, connected near the patient 4. Further measurement meters can also be disposed at different sites in the inspiration line 14 as the second patient parameter meter 30, in the expiration line 16 as the third patient parameter meter 32 or even within the patient as indicated with a fourth patient parameter meter 34.

The ventilator 2, the patient parameter meters 28, 30, 32, 34, the inspiration line 14 and the expiration line 16 alltogether form a ventilator system, where the inspiration line 14 and the expiration line 16 constitute a connection system. In the connection system humidifier, dehumidifier, bacterial filter etc, are normally located (but not shown in the figure).

The connection system will influence the respiratory gas pattern generated at the inspiration section 8. In particular, the respiratory gas pattern, set by a physician on the ventilator 2, will change before it reaches the patient 4. In order to compensate the generation of the respiratory gas pulse for this influence, thereby ensuring that the patient will receive the set respiratory gas pattern, measurements are made on a test gas pulse generated by the inspiration section 8 before the patient 4 is connected to the ventilator system. In figure 2 one test gas pulse is shown. The test gas pulse 36 comprises several pressure levels and is intended to include most of the pressure and flow characteristics which are present in the different modes intended to be used for the patient or are possible to use with the ventilator system. Instead of using one test pulse, several test pulses, selected from different modes of operation can be used. It is also possible to use only one test pulse selected from one of the modes. However, using a test gas pulse comprising several flow and pressure characteristics, provides for a faster and more accurate determination of the compensation required.

The test pulse 36 also includes a change in gas composition indicated at designation 38. The first part of the test pulse 36, indicated as area 40 will therefore comprise one gas composition and the second part of the test pulse 36, indicated as area 42 will comprise another gas composition. It should be noted, however, that a change in the composition of gas is not necessary for the method according to the invention, but it provides an accurate and easy locatable marker for later synchronisation (as described below).

As the test gas pulse 36 is delivered, measurements will be made at one or several sites, as indicated by the patient parameter meters in figure 1. One resulting test pulse response 44 is shown in the diagram in figure 2. By identifying the certain point in time (designation 38) where the gas composition is changed, a

time delay Δt for the connection system can be identified and the two curves 36, 44 can be synchronised in order to obtain a calibration curve 46. The calibration curve 46 basically indicates how the generation of a respiration gas pulse with a specific pressure and flow pattern must be compensated in order to ensure that a specific gas pulse pattern, set by a physician, reaches the patient. The correction can be obtained by using the pressure step in the test pulse 36 that corresponds most accurately to the pressure step set by the physician and locate the corresponding portion of the correction curve 46.

In figure 2 the test gas pulse 36, response pulse 44 and calibration curve 46 are indicated as curves in a diagram. This has been done in order to visualise the method more clearly. In practice, it is more preferable to sample all information with a specific sample rate, for instance 50-200 Hz and store it as data sets in a memory in the control unit. One data set for the test gas pulse and one or several data sets for the measured information and calibration factors. The correction data set can even be a look-up table, where the settings made by a physician for the respiration gas pattern to the patient is entered on the ventilator and used as entry code for the look-up table, thereby obtaining the relevant correction factor required for achieving the selected respiratory gas pattern as a read-out from the look-up table.

A correction data set can be obtained by forming the difference between a data set comprising set parameters for the test gas pulse and a data set comprising measured parameters at the connection site for the patient. The difference is formed after the data sets have been synchronised by identifying the change in the composition of gas.

An alternative way of synchronising the data (and determining the delay time) is to include and identify specific pressure and/or flow flanks. It is also possible to use a complex test gas pulse or series of test gas pulses and use mathematical methods for matching the information (e.g. least square method or similar). The latter, however, requires more calculation power.

The obtained measurements also comprise information such as resistance and compliance of the connection system (or measured parts of the connection system). By measuring at several sites, the connection system can be analysed partially. Hereby, information of the influence of single elements within the connection system can be obtained.

As already stated above, the test gas pulse 36 will be delivered before the patient is connected to the connection system. The open end of the connection system, where the patient will be connected may either be blocked or connected to a simulated lung (dummy), for instance a gas bag or an artificial respiration system with predetermined characteristics. After the patient is connected to the connection system a new test gas pulse or pulses may be supplied and new measurements be made. Based on the new measurements and the previous measurements (before connecting the patient) the influence caused by the patient can also be determined, whereby diagnostic information (such as resistance and compliance) can be obtained for the physician to further determine the following therapy to be given to the patient.

Figure 3 shows a simple block diagram structure of the control unit 26, where a first memory or data table 48 collects the set parameters for a respiration gas pattern or test gas pulse and a second memory or data table 50 collects the resulting measured parameters. The data from the two memories or data tables 48, 50 are transferred to a calculating unit, where a substraction of the two data tables are made after synchronisation for obtaining the third data table or data set, which includes the required calibration factors for the reference signal generator or control system signals which controls the inspiration section and the expiration section.

The present method may be used in a similar way for all kinds of respirator or ventilator systems, including anaesthetic systems.

Claims

1. A method of operating a ventilator system, comprising a ventilator and a connection system for, when connected to a patient, conveying gas to and from the patient, **characterized by** the method steps of

   setting a number of operational parameters for a test gas pulse,
   storing the set operational parameters as a first data set,
   delivering the test gas pulse,
   measuring parameters of a resulting gas pulse response,
   storing the measured parameters as a second data set, and
   forming a third data set based on the first data set and the second data set, said third data set comprising information relating to the static and dynamic influence and/or properties of at least one flow path within the ventilator system.

2. Method according to claim 1, **characterized in** that the first data set and the second data set are synchronised before the third data set is formed.

3. Method according to claim 1 or 2, **characterized by** the further steps of

   including a change in the composition of the gas in the test gas pulse,
   identifying the point of time for change in the composition of the gas in the first data set and in the second data set, and

syncrhonising the first data set and the second data set based on the identified points of time.

4. Method according to any of the above claims, **characterized in** that the third data set is obtained by subtracting the second data set from the first data set.

5. Method according to to any of the above claims, **characterized in** that the generation of a respiratory gas pattern by the ventilator system according to set operational parameters is adjusted according to the content of the third data set.

6. Method according to claim 5, **characterized in** that the third data set is stored as correction factors in a look-up table, where the set operational parameters are used as an entry code to the look-up table for obtaining a relevant correction factor.

7. Method according to any of the above claims, **characterized in** that the procedure of claim 1 is repeated after connection of a patient to the ventilator system, thereby obtaining a fourth data set which together with the other data sets comprise diagnostic information of the static and dynamic properties of the patient's respiration system.

8. Method according to claim 7, **characterized in** that the fourth data set is utilised for forming a fifth data set, and the generation of a respiratory gas pattern by the ventilator system according to set operational parameters is adjusted according to the content of the fifth data set.

9. Ventilator system (2, 14, 16) comprising an inspiration section (8) for generating an inspirational respiratory gas pattern, a connection system (14, 16) for, when connected to a patient (4), conveying gas to and from the patient (4), an expiration section (18) for generating an expirational respiratory gas pattern, a measurement system (10, 12, 20, 22, 28, 30, 32, 34) for measuring respiratory gas pattern parameters at different sites in the ventilator system (2, 14, 16) and a control unit (26) for controlling the operation of the ventilator system (2, 14, 16) based on set operational parameters and measured parameters, **characterized in** that the control unit (26) controls the inspiration section (8) and expiration section (18) to generate a test gas pulse based on set operational parameters for the test gas pulse, the control unit (26) comprises a data storage and calculation system (48, 50, 52) for storing the set operational parameters as a first data set and for storing parameters measured by the measurement system (10, 12, 20, 22, 28, 30, 32, 34) as a second data set and the data storage and calculation system (48, 50, 52) forms a third data set based on the first data set and the second data set.

10. Ventilator system according to claim 9, **characterized in** that the data storage and calculation system (48, 50, 52) synchronises the data in the first data set and in the second data set before the third data set is formed.

11. Ventilator system according to claim 10, **characterized in** that control unit (26) controls the inspiration section (8) to include a change in the composition of the gas in the test gas pulse, the data storage and calculation system (48, 50, 52) synchronises the data in the first data set and in the second data set by identifying the point in time at which the composition of the gas is changed.

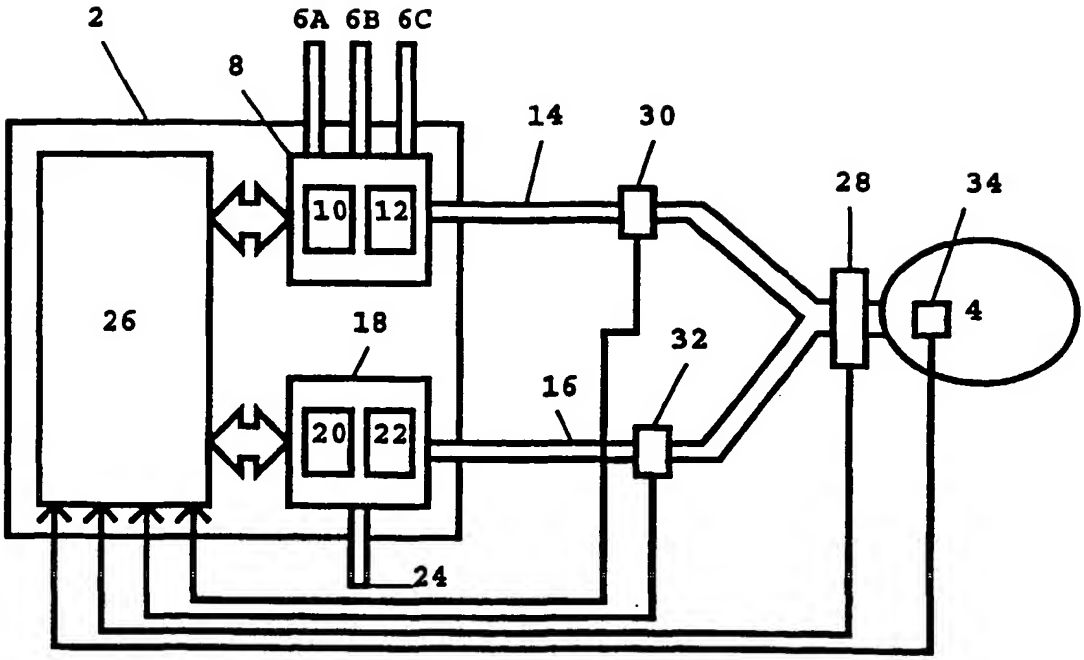
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FIG. 1

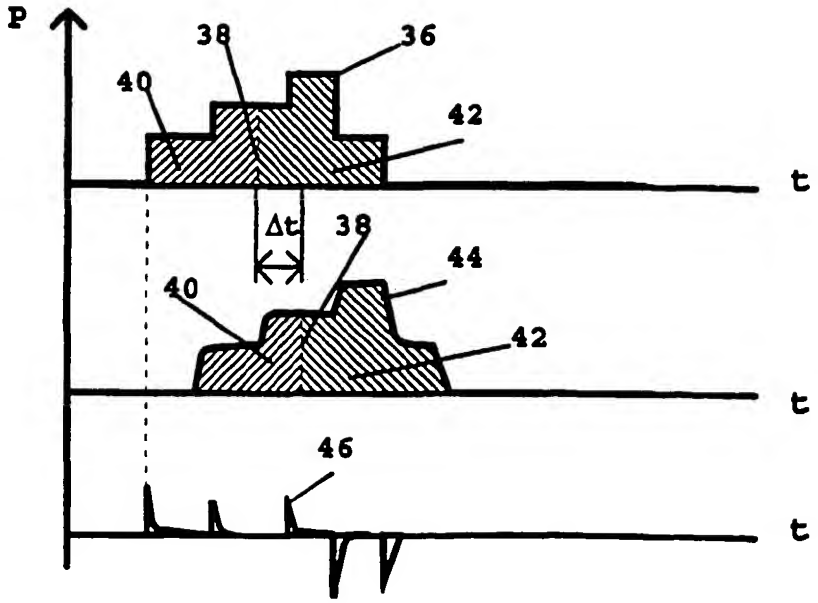
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FIG. 2

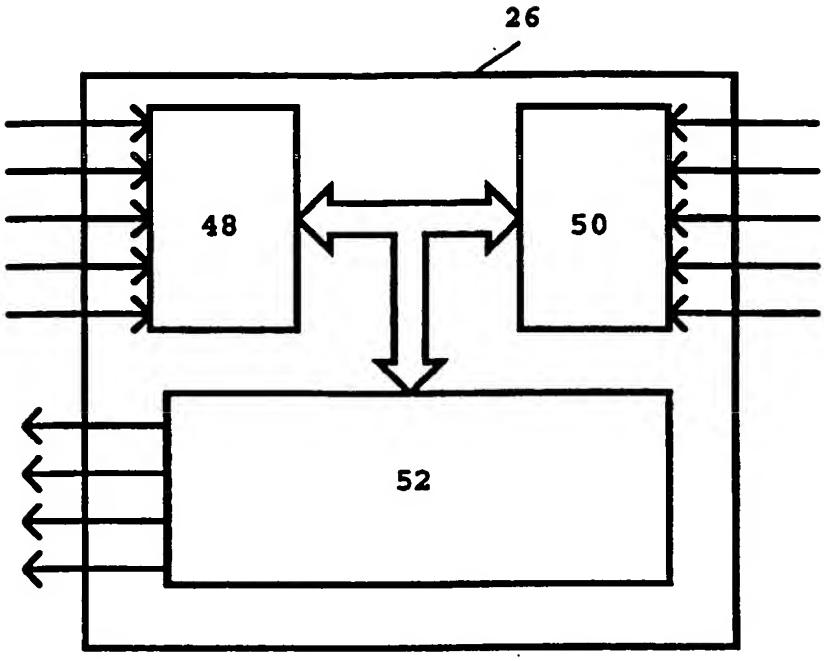

FIG. 3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 10 9023.8

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	EP 0723785 A1 (SIEMENS ELEMA AB), 31 July 1996 (31.07.96) * see the whole document *	1-11	A61M 16/00
A	WO 9516484 A1 (TEMPLE UNIVERSITY - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION), 22 June 1995 (22.06.95) * pages 6,70,71 *	1-11	
A	US 5303698 A (R.L.TOBIA ET AL.), 19 April 1994 (19.04.94) * column 9, line 33 - column 14, line 15 *	1-11	
A	US 4393869 A (A.BOYARSKY ET AL.), 19 July 1983 (19.07.83) * column 2, line 56 - line 66 *	7,8	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	21 October 1997	TOMMY SOMLO

CATEGORY OF CITED DOCUMENTS

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